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Expert Witness Report of Dr. Charles Stratton

I. Background, Experience and Training

I am a licensed Medical Doctor in the State of Tennessee with specialty in the areas of internal medicine and infectious disease. Since 1979, I have been active in the fields of internal medicine and infectious disease as both an attending physician and as a consulting physician at Vanderbilt University Medical Center, Nashville Veteran's Administration Medical Center, St. Thomas Hospital and the Stallworth Rehabilitation Hospital.

I have also served as the Director of the Clinical Microbiology Laboratory at the Vanderbilt University Hospital, and have taught infectious diseases and clinical microbiology to Vanderbilt University Medical Center medical students, residents, fellows, and other faculty members first as an Assistant Professor of Medicine and then as a tenured Associate Professor of Medicine and Pathology.

My responsibilities as a physician in the medical specialties of internal medicine and infectious diseases have encompassed prevention, diagnosis and treatment in a variety of health care settings. I currently make Clinical

EXHIBIT 2

Microbiology/Infectious Disease Rounds five days per week with Pathology Residents and Infectious Disease Fellows as well as do Clinical Microbiology/Infectious Disease Consultations as requested.

I graduated from the University of Vermont College of Medicine with a Doctor of Medicine degree in 1971. I completed my residency training in internal medicine at the University of Colorado Medical Center in 1974, and in 1976 completed a fellowship in infectious diseases and clinical microbiology at the University of Colorado Medical Center. I was board certified by The American Board of Internal Medicine in 1974, The American Board of Internal Medicine in the subspecialty of Infectious Disease in 1976, The American Board of Pathology in the subspecialty of Medical Microbiology in 1978, and The American Board of Medial Microbiology in Public Health and Medical Microbiology in 1979. My training and qualifications are more fully set out in my Curriculum Vitae, which is attached hereto as Exhibit 1, and incorporated herein by reference.

My opinions set forth herein are based upon my review of publicly available investigative materials about the ConAgra peanut butter *Salmonella* outbreak, materials produced by ConAgra, and my professional training, knowledge and experience.

II. Characteristics of *Salmonella*

Salmonella is a known bacterial pathogen of humans. It is colorless, odorless, microscopic and not detectable by normal senses.

Salmonella is a bacteria that lives in the intestines of warm blooded animals, including birds and rodents. *Salmonella* are transmitted from animal to human or from human to human. Humans are infected with Salmonella almost solely by the ingestion of contaminated food or drink.

When *Salmonella* is ingested, the bacteria multiply in the small intestines and colon. The typical clinical course of *Salmonella* infection is characterized by fever, abdominal pain, and diarrhea that persist for three to five days. Nausea and vomiting are common initial symptoms. These conditions typically subside within five days, but may last for as long as two weeks. Patients typically develop symptoms within one to two days, but there have been reports of patients developing symptoms as early as six hours or as late as several weeks after ingestion.

Most *Salmonella* infections follow a mild to moderate course without appreciable morbidity or mortality. Serious illness, however, is common in infants, in the elderly, and in persons with underlying diseases. Dehydration consequent to diarrhea may also lead to serious complications. *Salmonella* infections can also lead to Reiter's Syndrome. Recent studies have shown that

chronic *Salmonella* infection can have serious, long-term effects including intestinal fibrosis and Irritable Bowel Syndrome.

Ingestion of a tiny amount of food contaminated with Salmonella or other similar pathogens can result in infection. Moreover, in a food that is high in fat content, such as peanut butter, illness can arise from consumption of even fewer bacteria because the fat shields the bacteria from the stomach's normal defenses.

III. The ConAgra Peanut Butter *Salmonella* Outbreak

According to the Centers for Disease Control MMWR report of June 1, 2007, as of May 22, 2007, a total of 628 individuals from 47 states had been infected with the outbreak strain of *Salmonella* Tennessee from consumption of ConAgra's peanut butter. (Exhibit 2). The CDC reported that confirmed cases stretched from symptom onset dates of August 1, 2006 until April 23, 2007. Additional CDC information dated September 20, 2007, reported that 714 individuals were sickened by ConAgra's tainted peanut butter. (Exhibit 3).

The CDC confirmed cases of illness from ConAgra's peanut butter with symptom onset as late as July 17, 2007, several months after the recall. In fact, the CDC noted that 28.2 percent of the confirmed cases had symptom onset dates of February 15, 2007 or later – after the recall. The

CDC also noted that 8.1 percent of the cases had symptom onset dates of April 14, 2007 or later. These findings led the CDC to conduct a supplemental questionnaire regarding the effectiveness of the recall. (Exhibit 3). It is generally accepted, and expected, that a significant number of individuals become ill from a recalled food after the recall. No recall is one hundred percent effective. It is expected and understood that individuals will reasonably ingest the recalled product after a recall. This happens for several reasons. In some cases, individuals either do not hear of the recall or do not understand it. In addition, people may assume that after a recall all contaminated product has been removed from stores and that any product at stores has been confirmed to be free of contamination. That many individuals ingested ConAgra's peanut butter in the months following the initial announcements of the recall is expected and reasonable.

Additionally, while the CDC data shows an epidemiologic curve related to this outbreak with initial symptom onset dates of July 29, 2006, it is highly likely and expected that other cases of illness caused by ConAgra's tainted peanut butter occurred prior to that date.

III. Causation Proof

The vast majority of people who were made ill by the *Salmonella* contained in ConAgra's peanut butter will not have a stool sample that was

tested and shows a *Salmonella* infection with one hundred percent certainty. This is true for several reasons. First, as is well known, physicians in the United States rarely perform stool cultures in patients with diarrhea. Thus, the majority of cases of infectious gastroenteritus, including *Salmonella*, are not confirmed by stool culture.

Furthermore, stool cultures often result in false negative findings, meaning the test does not detect *Salmonella* even though the patient has a *Salmonella* infection. Thus, doctors cannot rule out a *Salmonella* infection when an individual has provided a stool sample in which *Salmonella* was not detected. Many factors contribute to this well known fact, including the insensitivity of stool culturing, the technical ability of the lab, and the technique used in collecting the sample. The authors of "FoodNet Estimate of the Burden of Illness Caused by Nontyphoidal *Salmonella* Infections in the United States," CID 2004:38 (Suppl 3) S127-S134, found that stool cultures are not one hundred percent sensitive and variations in specimen collection and specimen transport procedures and laboratory error further decrease the sensitivity of stool cultures. That paper estimated stool cultures are only seventy percent accurate in detecting *Salmonella*. In chronic infections, stool cultures are even less accurate.

Because stool cultures are rarely performed and do not always detect *Salmonella* infections, doctors and epidemiologists employ other tools to determine when a person more likely than not was made ill by a contaminated food. The CDC publishes Case Definitions for Infectious Conditions under National Surveillance. Centers for Disease Control and Prevention, Case definitions for infectious conditions under public health surveillance, MMWR 1997;46(No. RR-10). These guidelines are commonly used to define outbreaks when they occur, and are widely accepted.

Under the CDC guidelines for a *Salmonella* outbreak, a "Confirmed Case" is one with a laboratory test confirming the presence of *Salmonella*. A "Probable Case" – in other words, one where more likely than not the person was infected by the outbreak – is defined s a case that is clinically compatible and epidemiologically linked to a confirmed case.

The term "clinically compatible" is defined in the CDC guidelines as "A clinical syndrome generally compatible with the disease, as described in the clinical description." The CDC clinical description of *Salmonella* infection is "An illness of variable severity commonly manifested by diarrhea, abdominal pain, nausea, and sometimes vomiting. Asymptomatic infections may occur, and the organism may cause extraintestinal infections." Thus, in this outbreak, patients who, within an appropriate time

from consumption of the peanut butter, suffered diarrhea, abdominal pain, nausea or vomiting are "clinically compatible."

The term "epidemiologically linked" is defined in this circumstance to mean a case in which a) the patient had been exposed to a point source of infection to which all confirmed case-patients were exposed and b) transmission of the agent by the usual modes of transmission is plausible. In this case, the confirmed case-patients were exposed to ConAgra's tainted peanut butter. Moreover, transmission of *Salmonella* through tainted peanut butter is plausible. Thus, in this case, an epidemiologically linked case is one in which a person ate ConAgra's tainted peanut butter.

To summarize, in this case, for those who (1) ate ConAgra's peanut butter and (2) suffered, within an appropriate period of time, clinically compatible symptoms, including diarrhea, abdominal pain, nausea or vomiting, it is highly likely that their illness was due to ConAgra's peanut butter.

IV. Testing of Peanut Butter is Unreliable

Testing peanut butter for the presence of *Salmonella* would be difficult and not determinative in ruling out contamination. First, the actual peanut butter eaten by the individual cannot be tested. All that can be tested is the peanut butter remaining in the jar.

Moreover, peanut butter has a low moisture content such that bacteria will not multiply and spread through a jar of peanut butter as it might in a different medium. Thus, a sample from one part of a jar of peanut butter may be free of *Salmonella* while others, that might not be tested, do contain *Salmonella*. The properties of peanut butter make it very likely for *Salmonella* to exist in pockets or layers within the peanut butter. Unless all peanut butter is tested, one could not say with any certainty that no bacteria is present in the peanut butter jar.

The difficulty in detecting pathogens in foods is a reason why food manufacturers should not rely on finished product testing to control food safety. Instead, HACCP plans must be created to identify the critical control points (called "CCP"s) in food manufacturing, and the methods employed at the critical controls points must be tested and re-tested to confirm that the process works to control the hazard. In ConAgra's peanut butter plant, the only critical control point for biological hazards was the roaster. Thus, a reasonable manufacturer of peanut butter under these circumstances would carefully monitor the peanut roaster to be certain it eliminated biological risks. As discussed below in more detail, however, ConAgra knew from at least late 2004 that its roaster was not eliminating biological hazards and did not meet the requirements of ConAgra's HACCP.

In this case, the limitations in finished product testing were well demonstrated by the fact that ConAgra, itself, did not detect the contamination of its own peanut butter. The contamination was instead uncovered by the work of the CDC in its epidemiological study of the *Salmonella* Tennessee outbreak.

V. Killing Salmonella in Peanut Butter

Salmonella is well known to the food industry, and is specifically known to be a contamination risk for peanut products. An outbreak of *Salmonella* in Australia in 1996 was tied to peanut butter. Another reported outbreak of *Salmonella* in Australia was linked to peanut products in 2001. In 2000 a group of researchers for the Center for Food Safety and Quality Enhancement at the University of Georgia conducted a study and published an article regarding the "survival characteristics" of *Salmonella* in peanut butter.

It is expected that peanuts, which grow in the ground, may be contaminated with fecal-borne bacteria, including *Salmonella.* Heat can kill *Salmonella.* As shown in its HACCP plan, in ConAgra's Sylvester, Georgia plant, the peanut roaster was the only step to kill *Salmonella.* (Exhibit 4). In other words, the only thing done in ConAgra's peanut butter plant to eliminate harmful bacteria was putting the peanuts through the roaster. The

roaster was ConAgra's only critical control point for biological hazards.

The Sylvester plant detected Salmonella in its peanut butter in late 2004. (Exhibit 5). In response, ConAgra conducted a "Peanut Roaster Temperature Distribution Study" in January, 2005. (Exhibit 6). That study revealed that there were temperature differences along the roaster belt of as much as 100 degrees. The study also demonstrated that the roaster was not providing the heat required by ConAgra's HACCP plan -- 300 degrees for at least five minutes. Independent and internal inspections of the roaster concluded that it should be replaced.

A report titled, "Microbial Inactivation at Sylvester's Roaster & Roasting Time-Temperature Parameters" set forth requirements for a 4 log reduction in *Salmonella* during dry heat roasting. The conclusions included that peanuts must be roasted at 280 degrees for 18.1 minutes, or 300 degrees for 4.4 minutes. Based on ConAgra's study of it, the Sylvester roaster was not capable of meeting these requirements. Yet, ConAgra continued to use that roaster in 2005, 2006 and in 2007-- until the CDC discovered the *Salmonella* contamination and peanut butter production was stopped.

Furthermore, ConAgra used the lowest grade of edible peanuts, resulting, as described in ConAgra internal documents, higher "micro's." ConAgra noted that is competitors use "medium" grade peanuts, which have

a lower "micro count." ConAgra had used higher grade, lower contamination peanuts in the mid-90s but changed to the lower grade peanuts as a cost cutting measure. The lower grade peanuts were, "high in small and immature peanuts." Peanuts, when contaminated with microbiological organisms, will be contaminated on the surface. The more surface areas, the greater numbers of microbiological organisms. Thus, pound for pound, smaller peanuts have higher counts of microbiological organisms. Despite its knowledge that the roaster could not eliminate harmful bacteria, and that the cheaper peanuts it chose to use contained higher level of bacteria than the higher grade peanuts its competitors used, ConAgra continued to use the lower grade peanuts in its roaster.

In summary, ConAgra knew from at least late 2004 that it was not eliminating biological hazards from its peanut butter. ConAgra suspected the roaster, which was originally designed to operate as a blancher – not a roaster. By January 2005, ConAgra confirmed that the roaster was not meeting its critical control points requirements, and was not therefore eliminating biological hazards from its peanut butter. ConAgra further knew that its choice of the lowest grade of edible peanuts meant that its peanuts had higher levels of harmful bacteria than its competitors. Yet, despite this knowledge, ConAgra continued to use its roaster, making peanut butter day

after day, month after month, year after year – until the CDC detected that the peanut butter had caused a widespread *Salmonella* outbreak. ConAgra's actions were reckless, unjustifiable and demonstrated a conscious indifference to the serious food safety consequences arising from its behavior.

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